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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,550	02/24/2004	Bernd Thureau	MDX / 291US	8154

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EXAMINER
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NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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08/14/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/785,550

Applicant(s)

THURAU ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-114 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,17-19,44,45,51,60,61,67-81,89,90,97,98,101,106,108-112 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,10-16,20-43,46-50,52-59,62-66,82-88,91-96,99-100,102-105,107,113-114 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. This Office Action is responsive to the amendment filed 6/1/2007. Claims 1, 38, 58, 82, 95, 103, 113, and 114 are amended. Claims 67 and 108 are also amended. Claims 8-9, 17-19, 44-45, 51, 60-61, 67-81, 89-90, 97-98, 101, 106, and 108-112 remain withdrawn. **Claims 1-7, 10-16, 20-43, 46-50, 52-59, 62-66, 82-88, 91-96, 99-100, 102-105, 107, 113-114** remain pending.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1-7, 10-16, 20-29, 31, 34, 37, 82-88, 91-92, 95-96, 99-100, 103-105, and 113** are rejected under 35 U.S.C. 103(a) as being unpatentable over Alden et al (US Pub No. 20050101979) in view of Hagen et al (US Pat No. 6348043).

4. In regard to **Claims 1, 5-7, 11, 31, 82, 86-88, 95-96, 103, and 113**, Alden et al disclose a reservoir for use in a closed blood sampling system, the reservoir comprising:

a lower housing having a rigid wall including "first side" (308), best seen in Figure 3 bottom, with an opening opposite said wall;

a flexible membrane, referred to as "diaphragm" (310), overlying at least part of the rigid wall and sealingly secured thereto closing off the opening to define a variable volume chamber (300) therebetween;

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a channel formed in the rigid wall having an inlet port (304) and an exit port (312) and in fluid communication with the chamber, the fluid communication between the exit port and chamber being bidirectional due to exit port 312 allowing both flow into the chamber as well as flow out of the chamber through exit channel 318 (§0025 lines 15-18);

an upper housing coupled to the lower housing, best seen in Figure 3 top on the side of "duct" (320);

the flexible membrane having a minimum volume position spaced closely adjacent the rigid wall to define a minimum volume at which fluid still flows between the inlet port and exit port through the chamber, the flexible membrane being able to flex out of the minimum volume position to an expanded volume position (§0025).

5. However, Alden et al do not disclose a drive surface adapted to engage against the flexible membrane to hold said membrane in the minimum volume position. Alden et al do disclose that mechanical means may be used to control movement of said flexible membrane (§0025). Hagen et al disclose an analogous reservoir comprising a flexible membrane (70) coupled to a drive surface attached to a moveable plunger, referred to as "piston" (20), with a portion for manipulation by a user, wherein movement of the piston between two positions (Figure 18A and C) causes subsequent movement of the flexible membrane, best seen in Figures 18A-C (Col.10: 10-33).

6. Therefore, it would have been obvious to one of ordinary skill in the art to modify the reservoir of Alden et al to include a drive surface in the form of a moveable plunger having a first portion received through the upper housing with the drive surface coupled to the top of the flexible membrane and thus fluidly isolated from the chamber, said plunger having a portion for

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manipulation by a user, as taught by Hagen et al, such that movement of the plunger in one direction flexes the membrane toward the expanded volume position to allow sampling and movement in a second direction flexes the membrane toward the minimum volume position and holds the membrane in said position to discharge fluid from the reservoir, as an effective means to control the movement of the flexible membrane of Alden et al.

7. In regard to **Claims 2, 83**, Alden et al disclose the rigid wall including a stem adapted to cooperate with a mounting bracket for mounting to a support, best seen in Figure 2A and 2B.

8. In regard to **Claims 3, 84**, Alden et al disclose the rigid wall having a shape and the flexible membrane (310) generally conforming to the shape of the rigid wall.

9. In regard to **Claims 4, 85**, Alden et al in combination with Hagen et al disclose the rigid wall having a shape and the drive surface generally conforming to the shape of the rigid wall.

10. In regard to **Claims 10, 91**, Alden et al disclose the flexible membrane (310) having a lower surface, the rigid wall engaging against at least a portion of the lower surface in the minimum volume position.

11. In regard to **Claims 12, 92**, Alden et al in combination with Hagen et al disclose the flexible membrane having an upper surface, the drive surface engaging against substantially the entire upper surface when in the minimum volume position.

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12. In regard to **Claims 13-14, 99, 104**, Alden et al in combination with Hagen et al disclose the drive surface being positioned to move the membrane toward the rigid wall or channel so as to reduce the volume of the chamber stepwise in a first direction of movement of the drive surface.

13. In regard to **Claims 15-16, 100, 105**, Alden et al in combination with Hagen et al disclose the flexible membrane being able to flex away from the rigid wall or channel to the expanded volume position in a second direction of movement of the drive surface causing a stepwise increase in the volume of the chamber

14. In regard to **Claims 20-29, 34, and 37**, Alden et al in combination with Hagen et al disclose the invention above including a rigid wall with an upper edge, a flexible membrane with an upper edge, a housing with a lower edge, and a drive surface, all with a shape, but do not explicitly disclose a specific shape for said components. However, it would have been obvious to modify the rigid wall, flexible member, housing, and drive surface to have a shape such as bowl shaped, such that the rigid wall and flexible member are one of hemispherical, conical or oval bowl shape, the drive surface also bowl shaped, and the upper edge of the rigid wall and flexible member as well as the lower edge of the housing having a shape traversing at least one of a circular and elliptical path because it appears the invention of Alden et al as modified by Hagen et al would perform equally well with those shapes and such a modification would have been considered a mere design choice which fails to patentably distinguish over Alden et al in combination with Hagen et al.

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15. Similarly, in regards to **Claim 26**, it would have been obvious to modify the position of the inlet and exit ports of Alden et al as modified by Hagen et al to be adjacent to the upper edge of the rigid wall for the same reasons.

16. **Claims 30, 32-33, 35-36, 93-94, 102, 107** are rejected under 35 U.S.C. 103(a) as being unpatentable over Alden et al in view of Hagen et al, further in view of Bazell et al (US Pat No. 4370987).

17. In regard to **Claims 30, 102, 107**, Alden et al in combination with Hagen et al disclose the invention above but do not disclose the plunger having a knob for manipulation by a user. Bazell et al disclose a blood sampling device comprising an analogous plunger with a knob, referred to as "handle" (52), to allow easy access for manipulation by the user, best seen in Figure 5. Therefore, it would have been obvious to one of ordinary skill in the art to modify the plunger of Alden et al as modified by Hagen et al to include a knob as taught by Bazell et al for ease of manipulation by the user during device use.

18. In regard to **Claims 32-33, 35-36, 93-94**, Alden et al in combination with Hagen et al disclose the invention above but do not disclose at least one of the housing and plunger adapted to fix the drive surface in certain positions. Bazell et al disclose a blood sampling device comprising a housing, referred to as "barrel" (20), and a plunger, referred to as "piston" (40) and "rod" (50), said housing including a detent or "locking member" (28) adapted to engage a recess on the plunger, or "projections" (54), best seen in Figure 1 and 4 (Col.3: 28-51), as an effective

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mechanism to hold an analogous drive surface in a number of positions. Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Alden as modified by Hagen et al to such that the housing comprises a detent to engage a recess on the plunger, as taught by Bazell et al, to effectively secure the drive surface in a minimum or maximum volume positions

19. **Claims 38-43, 46-50, 52-59, 62-66, and 114** are rejected under 35 U.S.C. 103(a) as being unpatentable over Alden et al in view of Hagen et al, further in view of Simpson et al (US Pat No. 5002066).

20. In regard to **Claims 38, 58, 64, 114**, Alden et al in combination with Hagen et al disclose the blood sampling system comprising a reservoir above but do not disclose the system including tubing adapted to be coupled between a fluid supply and a circulatory system of a patient, nor a valve. Simpson et al disclose a closed blood sampling apparatus comprising tubing adapted to be coupled between a fluid supply (16) and a circulatory system of a patient, a sampling site (29) disposed in the tubing intermediate the patient, and a valve, referred to as "stopcock" (11), which is closed prior to sampling blood, as well as a "T-connector" (27) used along with a "storage syringe" (35) assembly that functions analogously to said reservoir, best seen in Figure 1 (Col.3), as an effective method and system to sample blood.

21. Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Alden et al as modified by Hagen et al to include tubing coupled between a fluid supply and a circulatory system of a patient so that a sampling site is disposed in the tubing



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intermediate the patient along with a valve that is closed prior to sampling blood, as taught by Simpson et al, and to sample the blood using the reservoir of Alden et al in combination with Hagen et al, as an effective method and apparatus to draw blood.

22. **Claims 52-57** are rejected under 35 U.S.C. 103(a) as being unpatentable over Alden et al in view of Hagen et al, further in view of Simpson et al, even further in view of Bazell et al. Alden et al in combination with Hagen et al and Simpson et al disclose the invention above but do not disclose the plunger with a knob or a recess to fixedly secure the drive surface by engaging a detent in the housing. Bazell et al disclose a plunger with a knob and a recess and the housing with a detent, as further described above. Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Alden et al as modified by Hagen et al and Simpson et al to include a knob and recess on the plunger and detent on the housing, as taught by Bazell et al, to improve the sampling device for the reasons previously explained above.

### ***Response to Arguments***

23. Applicant's arguments filed 6/1/2007 have been fully considered but they are not persuasive. Applicant contends that Alden et al do not disclose the fluid communication between the exit port and the chamber is bidirectional. However, it is noted that Alden et al clearly disclose that "a single check valve (at the location 312) may be present controlling both flow into the chamber 300 via the blood transport capillary channel 304 and flow out of the chamber 300 into an optional alternate exit channel 318" (¶0025 lines 15-18). Valve 312 must

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be bidirectional for this to occur. Thus, Alden et al disclose an inlet port 304, an exit port 312, and fluid communication between the exit port and chamber as bidirectional.

### *Conclusion*

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN  
8/7/2007

  
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